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Original Article

Evaluation of progression from first to second stage sacral neuromodulation and unplanned device removal

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ABSTRACT

Objective: Sacral neuromodulation (SNM) is an advanced treatment option for patients with refractory overactive bladder (OAB) symptoms, urinary retention, and bowel disorders; it is usually performed in 2 separate procedures. This study aims to determine a cohort's progression rate from stage 1 to 2 and predict factors for progression and unplanned device removal or revision.

Material and methods: A retrospective review was conducted in patients who underwent SNM at a single institution between June 2012 and May 2019. Progression rates from stage 1 to 2, patient characteristics, and indications for unplanned SNM removal or revision were recorded. Chi-square, Mann-Whitney U, and Fisher's exact tests were used for data analysis.

Results: A total of 128 patients underwent SNM for 1 or more of the following diagnoses: OAB (n=103), urinary retention (n=15), neurogenic bladder dysfunction (n=4), fecal incontinence (n=2), and constipation (n=4). The progression rate to stage 2 was 92.2% (118/128). Patients who failed to progress to stage 2 had additional diagnoses other than OAB, such as urinary retention or bowel disorders (p=0.007). Fifteen patients (12.7%) required SNM removal or revision within 4 years of surgery. Among these patients, the body mass index was significantly lower (p=0.036).

Conclusion: Most patients (92.2%) progressed to stage 2. Patients with only OAB symptoms had a higher progression rate to stage 2. Single full-stage procedures may be considered in select patients to reduce morbidity, time, and costs.

Keywords: First and second stage sacral neuromodulation; full-stage sacral neuromodulation; overactive bladder.

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Introduction

Sacral neuromodulation (SNM) is an advanced treatment option for patients with refractory overactive bladder (OAB) symptoms including urgency, frequency, and nocturia. SNM has also been shown to improve non-obstructive urinary retention and fecal incontinence.[1,2] Implantation of the SNM device typically entails 2 stages. During stage 1, a tined lead is placed at the level of S3 to stimulate the sacral nerve roots under fluoroscopy guidance. Optimal lead placement is confirmed intraoperatively by testing motor and sensory responses. After the lead placement, the patient is evaluated during a 1- to 2-week testing phase for symptom improvement.[3] If patients experience a 50% or greater improvement of their symptoms, they undergo the second stage, which involves placement of an internal pulse generator (IPG).[1]

Direct full-stage implantation combines stages 1 and 2 so that the lead and IPG are placed in 1 surgery. Although staged SNM is still standard practice, full-stage procedures may provide several benefits when compared with staged procedures. Full-stage procedures can avoid the risk of an additional surgical procedure, reduce costs and resources for the health care system, and shorten patients' recovery times.[4,5]

The literature indicates that certain demographic factors and patient characteristics may

influence SNM outcome. These parameters are not yet well defined. Reported factors associated with a higher progression rate to the second-stage SNM procedure were age <55 years, female gender, and absence of neurogenic conditions, whereas other studies have found no relationship between these factors and progression to second-stage SNM.[6-9]

The primary aim of this study is to determine the progression rate from stage 1 to stage 2 in our cohort and factors predictive of stage 2 progression. The secondary aim is to determine conditions associated with unplanned device removal or revision.

Material and methods

This study is a single-center, retrospective review approved by the institutional review board at our institution (IRB #5190157). Data was obtained through chart review from patients who underwent SNM therapy from June 2012 to May 2019 by 5 surgeons with SNM implantation experience applying the lead placement technique as described by Liberman et al.[10]

Selection criteria for SNM therapy and indications for removal or revision

Patients were selected for SNM therapy for refractory OAB symptoms if they failed at least 2 anticholinergic medications. SNM was offered as a third-line treatment option to patients with chronic bowel disorders[2,11,12] with failed dietary or medical treatments and to patients with non-obstructive urinary retention.[2,13,14] Patients were not candidates for SNM therapy if they had received a diagnosis of dementia or had an indication for magnetic resonance imaging (MRI) of their body. If the patient experienced ≥50% symptom improvement after lead implantation during stage 1, the patient progressed to implantation of the IPG during stage 2.

Removal or revision of the SNM device (lead and IPG or IPG alone) after stage 2 implantation was performed in patients who complained of pain associated with the device, experienced loss of efficacy, developed a postoperative skin infection, or required a body MRI.

Main Points:

- The progression rate from stage 1 to stage 2 SNM in this cohort was 92.2%, validating reports in the literature.
- Most patients progressing to stage 2 were diagnosed with only symptoms of refractory OAB (55.9%) and no other lower urinary tract symptoms or bowel dysfunction.
- In this cohort, patients who required SNM removal or revision were found to have a significantly lower BMI (p=0.036).
- Single full-stage procedures could be pursued in select patients with only refractory OAB symptoms to reduce morbidity related to an additional procedure and to save time and costs.

Chart review

Business Intelligence Tool (version 2019) was used to extract medical record numbers from electronic medical records (Epic, version 2018) for patients who underwent lead placement during stage 1, IPG placement during stage 2, and lead or IPG revision/removal within 4 years of surgery. We also recorded patients with a history of previous SNM. Patients from external referral centers who only underwent lead or IPG replacement were not included in this study. Patient information was de-identified into a database. Chart review was conducted to record demographic characteristics (e.g., age, body mass index [BMI], sex, race, history of smoking, alcohol use, and insurance type), medical history (e.g., comorbidities, history of mental health disorders, history of pain, frailty score) for each patient.

A frailty score was calculated for each patient to define frailty on a 4-point scale,[15] where 1 point was given for history of hospitalizations, history of emergency room visits, requiring assistance with ambulation, and abnormal gait.

Preoperative indication for SNM therapy was recorded (e.g., refractory OAB symptoms, non-obstructive urinary retention, neurogenic bladder dysfunction, fecal incontinence, and constipation). For patients with multiple indications, all diagnoses were recorded. Progression to stage 2 or failure to progress was recorded for all patients.

Reasons for unplanned device removal or revision within 4 years of surgery were analyzed. A procedure for removal or revision was considered unplanned if it was initiated because of a patient's complaint about the device and not because of the manufacturer's recommendation for IPG exchange.

Outcome measures and data analysis

The primary outcome was defined as patient progression from stage 1 to stage 2 SNM implantation. For the primary outcome, patients were divided into 2 groups: Those who progressed to stage 2 and those who did not progress. Factors associated with SNM progression were analyzed. The secondary outcome was defined as SNM removal or revision within 4 years of surgery. Similarly, for the secondary outcome, patients were divided into 2 groups: Those who did not undergo device removal or revision, and those who did. The parameters collected through chart review (above) were compared between groups for each outcome measure.

Statistical analysis

Categorical data was analyzed using chi-square analysis, and continuous data was analyzed using the Mann-Whitney U test. Fisher's exact test and the asymptotic significance test were used for evaluation to approximate p-values. Statistical significance was analyzed at the level of $p<0.05$. Data analysis was

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performed using IBM Statistical Package for the Social Sciences version 22 (IBM SPSS Corp.; Armonk, NY, USA).

Results

From June 22, 2012, to May 22, 2019, 128 patients underwent stage 1 SNM at our institution. Among all patients, the average age was 64.6 years (range 24–89), and 79.7% were female. The average BMI was 30.7 kg/m^2. In 52.3% (67/128) of patients, the BMI was <30 kg/m^2, whereas in 47.7% (61/128) of patients, the BMI was ≥30 kg/m^2. On average, 4 comorbidities were documented per patient.

In total, 103 patients (80.5%) were diagnosed with OAB, whereas 25 patients (19.5%) were diagnosed with another urologic or fecal disorder. Of the patients with OAB (n=103), 66 (64.1%) had pure OAB, whereas 37 (35.9%) had OAB plus an additional disorder. The remaining patients (n=25) were found to have at least 1 of the following diagnoses: urinary retention (n=15), neurogenic bladder dysfunction (n=4), fecal incontinence (n=2), or constipation (n=4).

There were 92.2% of patients (118/128) who progressed to stage 2 and 7.8% (10/128) who did not progress. Reasons for not progressing were failure of symptom improvement (9/10), and a skin infection in 1 patient (1/10) who consequently decided not to pursue further treatment.

Of the patients who did not progress to stage 2 (n=10), 90% (9/10) were diagnosed with 1 or more of the following diagnoses: urinary retention, neurogenic bladder dysfunction, or constipation. However, in the progression group, less than half of the patients (44.1%, n=52) were found to have 1 or more of these diagnoses (p=0.007).

There was a trend of female sex dominancy in the progression group compared with the non-progression group of 81.4% (96/118) versus 60% (6/10), respectively (Table 1). No difference was observed between the progression and the non-progression groups in terms of age, BMI, race, failed other advanced treatment options, total number of comorbidities, history of mental health disorders, history of chronic pain, frailty, history of smoking, alcohol use, or insurance type (Table 1).

Patients who progressed to stage 2 were followed for 4 years after surgery (mean: 1.13±1.5 years), where 12.7% (15/118) underwent SNM removal or revision. Although 10 patients underwent both IPG and lead removal, 5 patients underwent only IPG removal. We found that patients who underwent removal or revision (n=15) had a significantly lower BMI (27.8±5.8 kg/m^2) than the patients who did not undergo removal (n=103) (BMI: 31.3±6.6 kg/m^2) (p=0.036) (Figure 1). The reasons for removal or revision of the SNM device were buttock pain at the IPG implantation site (n=7), loss of efficacy (n=4), skin infection after surgery (n=3), and need for a body MRI (n=1). No differences were observed between the group with SNM removal or revision and the group without in terms of age, sex, race, diagnosis, failed other advanced treatment options, total number of comorbidities, history of mental health disorders, history of chronic pain, frailty, history of smoking, alcohol use, or insurance type (Table 2).

Discussion

SNM is a widely used advanced treatment option for OAB symptoms, non-obstructive urinary retention, and bowel disorders.[2,11] SNM implantation usually involves 2 stages with symptom testing between stages 1 and 2. In our study, we found a high progression rate from stage 1 to 2 of 92.2%, which is similar to progression rates of 90.3%,[3] 91.4%,[16] and greater than 69%[17] reported in the literature. Given the high progression rate to stage 2 and supporting data in the literature, one can argue that performing a single full-stage procedure without conducting a testing phase may be more efficient than performing a staged procedure.[18] A direct full-stage implantation can potentially reduce patient burden and costs from a second procedure.

Conversely, analysis of a national dataset showed that the progression rate from stage 1 to stage 2 was only 35%, which indicates that the success rate can vary based on volume and efficiency of each institution, the surgeon's experience, the patient population, patient education and characteristics, and the indications for SNM.[19] Most patients (80.5%) in our study received a diagnosis of OAB and progressed to the second stage with a

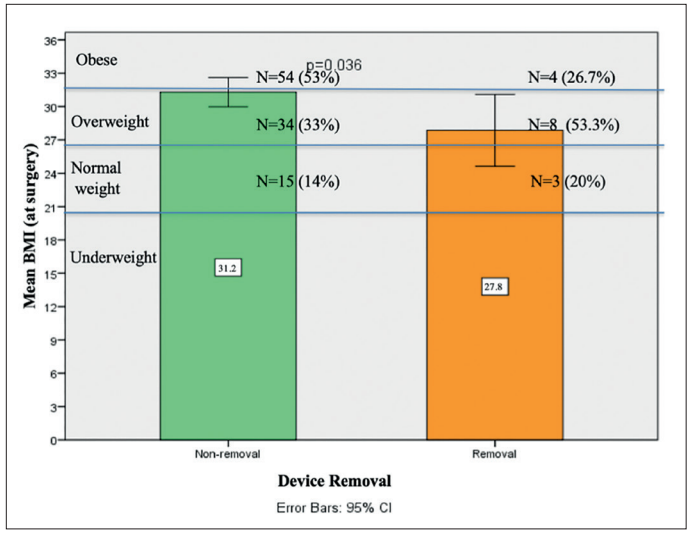

Figure 1. Comparison of mean BMI among patients undergoing SNM removal/revision versus no removal/revision
BMI: body mass index; SNM: sacral neuromodulation

Table 1. Patient characteristics for progression from stage 1 to stage 2 (group 1) compared with no progression (group 2)

Parameter	Group 1 (n=118)	Group 2 (n=10)	p
Age (years)			
Mean	64.8	62.9	0.480
Standard deviation	13.4	11.5	
BMI (kg/m^2)			
Mean	30.7	31.6	0.790
Standard deviation	6.5	9.0	
Sex, female, n (%)	96 (81.4)	6 (60)	0.118
Race, n (%)			
White	92 (78)	7 (70)	0.230
Non-white	26 (22)	3 (30)	
All diagnoses for SNM, n (%)			
Only OAB	66 (55.9)	1 (10)	0.007[#]
OAB and/or other diagnosis*	52 (44.1)	9 (90)	
Number of comorbidities			
Mean	3.6	3.3	0.652
Standard deviation	1.8	1.7	
History of mental health disorders, n (%)	47 (39.8)	4 (40)	0.620
Frailty score, n (%)			
0	36 (30.6)	2 (20)	0.132
1	41 (34.7)	3 (30)	
2	29 (24.6)	3 (30)	
3	3 (2.5)	2 (20)	
4	4 (3.4)	0	
Unknown	5 (4.2)	0	
History of smoking (present or former), n (%)	71 (60.2)	6 (60)	0.791
Alcohol use, n (%)			
Yes	47 (39.8)	2 (20)	0.432
No	70 (59.3)	8 (80)	
Unknown	1 (0.8)	0	
Insurance type, n (%)			
HMO	64 (54.2)	5 (50)	0.806
Medicare	35 (29.7)	4 (40)	
PPO	10 (8.5)	0	
Medi-Cal	7 (5.9)	1 (10%)	
No insurance	2 (1.7)	0	

*Other diagnoses include the following: urinary retention, fecal incontinence, neurogenic bladder dysfunction, and constipation. BMI: body mass index; HMO: health maintenance organization; OAB: overactive bladder; PPO: preferred provider organization; SNM: sacral neuromodulation

[#]Significant at $p<0.05$

success rate of greater than 90%. In addition, we found that a significantly greater percentage of patients in the non-progression group (9/10, 90%) were diagnosed with a urologic or fecal disorder other than OAB or in addition to OAB. The results of our study suggest that direct full-stage implantation could be considered in select patients who are more likely to progress to

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Table 2. Patient characteristics of patients with no indication for SNM removal/revision versus patients with SNM removal/revision

Parameter	No removal/revision (n=103)	Removal/revision (n=15)	p
Age (years)			
Mean	64.8	64.3	0.960
Standard deviation	13.2	16.0	
BMI (kg/m^2)			
Mean	31.3	27.8	0.036[#]
Standard deviation	6.6	5.8	
Sex, female, n (%)	83 (80.5)	12 (80.0)	0.723
Race, n (%)			
White	79 (76.7)	10 (66.7)	0.064
Non-white	24 (23.3)	5 (33.3)	
All diagnoses for SNM, n (%)			
Only OAB	57 (55.3)	8 (53.3)	1
OAB and/or other diagnosis*	46 (44.7)	7 (46.7)	
Number of comorbidities			
Mean	3.6	4.0	0.425
Standard deviation	1.7	1.9	
History of mental health disorders, n (%)	40 (38.9)	6 (40)	1
Frailty score, n (%)			
0	33 (32.1)	4 (26.7)	0.641
1	35 (33.9)	4 (26.7)	
2	22 (21.4)	6 (40)	
3	3 (2.9)	0	
4	4 (3.8)	0	
Unknown	6 (5.9)	1 (6.6)	
History of smoking (present or former), n (%)	57 (55.3)	13 (86.7)	0.073
Alcohol use, n (%)			
Yes	41 (39.8)	7 (46.7)	0.834
No	59 (57.3)	8 (53.3)	
Unknown	3 (2.9)	0	
Insurance type, n (%)			
HMO	56 (54.3)	7 (46.7)	0.508
Medicare	28 (27.2)	7 (46.7)	
PPO	9 (8.8)	1 (6.6)	
Medi-Cal	8 (7.8)	0	
No insurance	2 (1.9)	0	

*Other diagnoses include the following: urinary retention, fecal incontinence, neurogenic bladder dysfunction, and constipation. BMI: body mass index; HMO: health maintenance organization; OAB: overactive bladder; PPO: preferred provider organization; SNM: sacral neuromodulation
[#]Significant at p<0.05

stage 2, such as those who are diagnosed with only refractory OAB symptoms. This analysis may provide future clinical guidance when deciding whether to perform staged or direct full-stage procedures.

Direct full-stage SNM procedures can save patients' time, increase patient satisfaction, reduce morbidity, and generate a savings of $3,655 per patient when compared with staged procedures.[20] If the progression rate from stage 1 to stage 2 is greater than 90%, the cost savings is estimated to increase to more than $5,000 per patient.[21] Some single-payer health maintenance organization centers in the United States are already providing direct full-stage SNM for select patients.[18] However, a consensus has not yet been reached regarding whether staged procedures are the most efficient utilization for all SNM-naïve patients. A direct full-stage procedure has some benefits, including potentially reducing morbidity by eliminating an additional surgery, which could lower the anesthesia risk and infection rates. From a patient's perspective, direct full-stage procedures would reduce travel for medical care, time off from work, and potentially improve satisfaction. An argument against direct full-stage implantations is the potentially higher cost to the health care system by implanting an IPG for those who do not experience improvement of their urinary symptoms. If performed in a staged fashion, the IPG implantation and subsequent removal would have been avoided.

However, additional information about patient selection and progression rates needs to be considered before the adoption of direct full-stage implantation. Some studies indicate that certain patient characteristics are associated with SNM outcomes, but there is no reported consensus or other guidelines for patient selection.[6,7,22] For instance, Amundsen et al.[6] reported that SNM therapy for neurogenic bladder dysfunction had poorer outcomes, and younger patients have better outcomes with SNM. However, Anger et al.[8] found no association between age and progression. Anger et al.[7,8] also reported that female patients had a higher progression rate from stage 1 to stage 2 than male patients and hypothesized that the presence of a prostate in male patients leads to outlet obstruction and treatment-refractory bladder conditions.

In this study, we evaluated whether patient characteristics and indication for SNM therapy are associated with progression. We found that most patients who progressed from stage 1 to stage 2 were diagnosed with only refractory OAB symptoms, and patients diagnosed with chronic non-obstructive urinary retention or bowel symptoms progressed significantly less, which was similar to others' findings.[7,22] We also observed that more female patients progressed to stage 2 implantation than male patients, but unlike other studies,[7,8] this result was not statistically significant. In addition, we found that other medical and demographic characteristics were not associated with SNM progression. Our study differed in some ways to what is reported in the literature. We found that characteristics including age and history of psychiatric illness were not associated with SNM progression, unlike what has been previously reported.[7,23,24] The difference in the findings between our study and those in the literature may be explained by the variance of the study population and surgical indications.

Our study suggests that BMI may be a factor that could predict outcome with SNM implantation. We observed that patients who did not undergo device removal or revision had a significantly higher BMI than those who underwent removal/revision ($p=0.036$). This observation is similar to what was reported by Faris et al.,[22] who quantified that with each increase in BMI unit, there is a 5% decrease in the odds of SNM device removal. Among the patients who underwent removal or revision, the most common reason was pain at the buttock site, followed by loss of efficacy, skin infection after surgery, and need for a body MRI. This differed from what has been reported in the literature, where the loss of efficacy and postoperative skin infection were cited as the most common reasons for device explantation or revision.[25-28] The observed differences may be due to the small sample size of patients who underwent removal or revision in our study (n=15). As the primary reason for removal or revision in our population was pain at the buttock site, one can speculate that the non-removal group may have had more adipose tissue owing to the higher BMI providing additional support for the IPG. Therefore, a higher BMI could provide protection against buttock pain from the device and unplanned removal or revision. In contrast, an increased BMI may also increase the risk of a postoperative skin infection.[29] Larger studies are needed to further examine the impact of BMI on SNM outcome in order to improve clinical decision making.

We acknowledge that this study has several limitations. One limitation is the retrospective study design. We were only able to observe data previously recorded in the patients' charts. As not all of the patients completed pre- and postoperative symptom surveys or underwent pre- and postoperative urodynamic studies, we were confined to measuring SNM outcome as the progression from stage 1 to stage 2 surgery and SNM removal or revision after implantation.

Another limitation is our small sample size of patients who did not progress to stage 2 surgery (n=10) and who underwent IPG removal or revision (n=15). Therefore, our findings should be validated in randomized, prospective, multicenter studies.

Most patients (92.2%) in our cohort undergoing SNM implantation progressed to stage 2. Patients with a diagnosis of only OAB symptoms had a higher progression to stage 2 than those with OAB and/or additional symptoms of lower urinary tract dysfunction or bowel disorders, such as fecal incontinence and constipation. A higher BMI seemed to be protective against unplanned device removal or revision in our cohort.

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Direct full-stage SNM implantation can be considered in select patients with refractory OAB to reduce morbidity, time, and costs associated with an additional procedure.

Future prospective, randomized studies need to be performed to further evaluate factors associated with SNM outcome, as well as studies comparing the efficacy and cost-effectiveness of staged versus direct full-stage implantation.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of Loma Linda University Institutional Review Board (IRB # 5190157).

Informed Consent: Written informed consent was obtained from patients who participated in this study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept – A.F., A.S.; Design – J.G.; Supervision – F.J.; Resources – A.F., A.S.A.; Data Collection and/or Processing – J.G., F.J.; Analysis and/or Interpretation – A.F., A.S.A., J.G., F.J., A.S.; Writing Manuscript – A.F., A.S.A.; Critical Review – F.J.

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